ATTACHMENT A

Remarks

The requirement concerning the specification has been noted. It is believed that this format is not required in the present case since it is a national phase application of a PCT application.

This application now includes claims 55-86. More specifically, this application now retains previous independent claim 55 with previous and new dependent claims 56-72 and a new independent claims 73 with it's new dependent claims 74-86.

The rejections under 35 U.S.C. § 112 do not apply to the claims now present in this application and hence comments regarding the § 112 rejections are not necessary.

All claims rejected under § 102 have been cancelled (and will be the subject of a divisional application to be filed in due course) so that comments responsive to the § 102 rejection are not necessary.

Since this application now includes only independent claim 55 which is directed to the single anchor concept and independent claim 73, which is also directed to the same single anchor concept, the following remarks relating to patentability will respond only to the rejection of claim 53 and 55-65 as being obvious in view of the Marnay U.S. Patent No. 5,314,477.

For the following reasons, it is respectfully submitted that independent claims 55 and 73 as well has their dependent claims 56-72 and 74-86 are patentable over the Marnay U.S. Patent No. 5,314,477 ("the '477"). The essential portion of the Examiner's rejection, which is respectfully traversed and which is believed to be in error, is the statement appearing on page 15 of the Office Action that the '477 patent discloses two

anchors instead of one and therefore does disclose a single anchor (although not on the midline) and/or that it would have been obvious to one having ordinary skill in the art to modify the '477 patent to provide a single centered anchor. The basis for this rejection is the Examiner's position that taking one of the two anchors in the '477 patent and simply moving it to the midline would be a mere relocation of parts which would then be unpatentable, citing In re Japikse, 86 USPQ 70.

Contrary to the Examiner's allegation, the presently claimed single anchor implant would not have been obvious from the prior art. Although the Examiner alleges that a reference disclosing two anchors discloses a single anchor, a reference disclosing two anchors does not disclose a device affirmatively claiming a single anchor. While merely claiming one element may be disclosed by prior art which teaches more than one of the elements, reciting a negative limitation in the form of a "single" element is not disclosed by prior art which teaches more than one element. For example, in U.S. Patent No. 5,960,411, a patent directed to a single action method for processing an order for an item was deemed patentable over prior purchasing methods which required more than a single action. See, e.g., Amazon.com Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 57 U.S.P.Q.2d 1747 (Fed. Cir. 2001). Therefore, the claimed implant with a single anchor is not disclosed by the '477 patent. To the extent that the Examiner's rejection essentially perceives an implant with a single central anchor as being an obvious variation of an implant plate having a pair of anchors, nothing could be farther from the truth or more completely remote from the actual facts in the complex field of spine arthroplasty. One of the inventors of the present application is Dr. Marnay the sole inventor in the prior art '477 patent. As

explained in the attached declaration by Dr. Marnay, at the time of the '477 patent, it was considered very important to provide a pair of anchors for each of the upper and lower plates. When a time arrived that Dr. Marnay and his co-inventor herein came to consider the possibility of using a single central anchor, or keel as it referred to in this application, it was not at all obvious how this could be done. Consideration and development of this very different approach went on for well over five years before the single anchor implant was developed by Dr. Marnay and his co-inventor. The attached declaration of Dr. Marnay under 37 C.F.R. § 1.132 sets forth in considerable detail (1) why the original concept of a pair of anchors on each plate was thought to be necessary, originally precluding thought of a single anchor and (2) the tremendous advantages which have since been realized after and by the development of the single anchor concept.

The extensive and significant advantages achieved by the single anchor concept, as outlined in Dr. Marnay's Declaration, which advantages were not realized prior to development of the single anchor concept, clearly established that the single anchor concept is not only unobvious but very unobvious over the '477 patent.

In accordance with Dr. Marnay's Declaration, prior to the present invention, it was considered necessary to include two anchors in order for an implant to be functional (Declaration, paragraphs 6 and 7). The conventional thinking was that two anchors were necessary in order to provide adequate stability of the implant and to secure the implant sufficiently to the vertebrae (Declaration, paragraph 6). Further, it was believed that having two anchors ensured that at least one of the two anchors will be firmly implanted into the vertebrae should a portion of the vertebrae bone itself be deteriorated

(Declaration, paragraph 7). Thus, having two anchors increased the likelihood that the implant will be securely fixed to the vertebrae (Declaration, paragraph 7). Thus, the conventional state of the art and thinking of one of ordinary skill in the art prior to the present invention was that it was necessary to include two anchors in order for the implant to function properly and to be implemented as an intervertebral implant (Declaration, paragraphs 6 and 7).

Furthermore, although the state of the prior art taught the essential use of two anchors, the present invention overcomes the prior design limitation mandating two anchors through an extensive redesign of the prior implant of the '477 patent (Declaration, paragraph 9). Absent the research and development of the present Applicants, it would not have been possible to have successfully implemented a single anchor implant. In fact, over 5 years passed between the time Dr. Marnay developed the '477 implant to the time Applicants developed the present single anchor implant (Declaration, paragraph 9). The span of time which it took Applicants to develop a single anchor system evidences that the modification and transition from a two anchor implant to a single anchor implant was not merely a routine relocation of parts requiring only routine skill, (Declaration, paragraph 7).

Further, the present single anchor implant provides enhanced features not taught or suggested in the art, thereby providing secondary considerations of non-obviousness. Non-obvious and advantageous features which are provided by the present single anchor implant include insertion of an implant using an insertion instrument which makes it easier to center the implant between one's vertebrae. For example, a specially designed insertion instrument can be used which aligns the

instrument with the center anchor for easier centering of the implant relative to one's vertebrae (Declaration, paragraph 12). Also, the single anchor provides a center guide which can be checked using a fluoroscope followed by using a chisel to cut a slot in the vertebrae which ensures proper centering. In addition, a single anchor implant is less bulky than a two anchor implant thus making the present implant less invasive during insertion.

The present single anchor implant provides for a minimal invasive approach due to the reduced size of the implant which thus reduces the volume/size of the instrumentation required for implantation. An additional advantage of the present single anchor implant is that the single anchor is inserted between one's vertebrae in a portion of the vertebrae bone between two anterior vessels which could pose implantation complications when inserting a two anchor implant (Declaration, paragraph 13). Unlike the two anchor implant which requires a larger exposure of vessels and more extensive retraction, the present single anchor implant requires a smaller exposure. As a result, the present single anchor implant limits the potential risk to interior vessels, mainly the aorta and the vena cava, which if nicked or severed could result in the loss of blood, potentially six liters per minute.

Yet another advantage of the single anchor implant is that it provides for perfectly aligned upper and lower vertebrae slots to be chiseled simultaneously and thereby perfectly aligned with one another (Declaration, Paragraph 14). The prior two anchor implant did not allow for simultaneous upper and lower slots to be cut in the adjacent vertebral body as the vertebral space (and the entry space thereto between blood vessels) is not sufficiently large to accommodate a chisel which would cut both upper

slots and lower slots simultaneously. Thus, for example, the upper two slots were cut after the lower two slots, or vice versa, thereby resulting in possible non-alignment of the upper and lower slots. However, due to the minimal intervertebral space necessary in order to chisel a single superior and single inferior slot, one is now able to simultaneously cut both slots simultaneously thereby ensuring alignment of both the inferior and superior slots (Declaration, Paragraph 14)

Yet a further advantage of the present single anchor implant is that it provides for minimizing the risk to fracturing the vertebral body since only a single cut is made in each invertebral body. This advantage is even more relevant in situations in which adjacent two level disc replacement is necessary where the prior two anchor implant would have required four slots to be chiseled in a single vertebral body (i.e., two in the inferior base plate and two in the superior base plate of the single vertebral body). Accordingly, the present single anchor implant limits the risk of fracture by reducing the number of cuts in a vertebral body.

And a still further advantage of the present single anchor implant is that the present implant provides for enhanced flexibility of the geometry of the plates of the implant to match the anatomy of one's vertebral body plate.

In view of the above, it is respectfully submitted that this application is now in condition for allowance, which action is promptly and respectfully solicited.